K031575

NOV 1 4 2003

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

Submitter: VIASYS Healthcare GmbH
Leibnizstasse 7
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Germany

Contact:

(USA)
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Alternate (Germany)
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VIASYS Healthcare GmbH
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Reg. No.: 9615102

Date Preapared: April 28, 2003

B. Device

1. *Proprietary:* SpiroPro® SpO_2

2. *Common/Generic:*

   a) Calculator Pulmonary Function
   b) Diagnostic Spirometer and Pulse Oximeter

3. *Classification:*

   a) Calculator Pulmonary Function
   b) Diagnostic Spirometer and Pulse Oximeter

4. *Class:* Class II

5. *Panel Code:*

   a) BTY
   b) DQA; BZG

6. *Regulation Number:*

   a) §868.1890
   b) §870.2700; 8681840

C. Identification of Legally Marketed (Unmodified) Devices

Pulmonary Function

1. *Name:*	SpiroPro®
2. *Manufacturer:*	VIASYS Healthcare GmbH
3. *K Number:*	K000648
4. *Date Cleared:*	February 28, 2000

Pulse Oximetry

1. *Name:*	SpirOxCard®
2. *Manufacturer:*	QRS Diagnostic, LLC
3. *K Number:*	K001995
4. *Date Cleared:*	October 28, 1998

D. Description of the Device

The pocket spirometer SpiroPro® SpO_2 is a portable, electronic measuring device for the determination of expiratory and inspiratory parameters (Vcin, FVC, FEV1, MEF50 etc.) including Pre/Post testing, date and time stamps as well as the complete registration of spirogram and flow-volume curves by a very precise pressure transducer (pneumotachograph). The built-in interpretation module enables an easy quality check and an automatic selection of the best measuring result.
The unique SpO_2 option completes the range of functions of the versatile spirometer. SpO_2-spot and trend measurements can be performed also oxygen saturation and heart rate can be recorded over a period of 60 minutes.

Equipped with a graphical LCD display, an innovative touch-screen technology and a user-friendly graphical user interface, the SpiroPro® SpO_2 provides the latest developments in technology. The input of patient data and the selection of the menu functions is realised by just touching the corresponding icon with your finger tips.

The SpiroPro® SpO_2 can store up to 600 measurements in its non-volatile memory. If required also versions with higher capacity are available. The rechargeable battery allows an operation time of approximately 2 weeks. A charger that recharges the battery within 2 hours is supplied with the unit.

With the built-in communication module a direct printout of results and graphs to a PCL-compatible printer is possible. Of course, data transmission to and from a PC by a serial port is an integral part of the innovative concept. The optional software package "SpiroPro® SpO_2 for Windows" receives the data all-automatically and stores them on the PC.

The unit can work stand alone or in combination with a PC for measurements with real-time display, questionnaire functionality, data analysis and long term storage.

Combining the two diagnostic devices into one device is very cost effective for the user. A pulmonary function calculator and a pulse oximeter are two devices that a physician will use on a regular basis for patient care.
The handy, modular design allows the use of the SpiroPro® SpO_2 in many fields of primary care.

E. Intended Use Statement

The SpiroPro SpO2 is a portable, battery operated device and can be used by physicians in the office or hospital, in occupational medicine or by patients in the home. The SpiroPro SpO2 measures inspiratory and expiratory lung function parameters in adults and children 4 years and older. In addition to the pulmonary function measurements, oxygen saturation and heart rate can be recorded.

F. Required Components

- SpiroPro® SpO2 (with Nonin® Xpod Patient Cable Oximeter)
- Nonin Finger Clip Sensor
- Pneumotachograph set
- Plastic Disposable Mouthpiece
- User Manual
- Windows Software (Option)

G. Summary Table of Comparisons

The following summary tables of comparisons compare the modified device (SpiroPro® SpO_2) to the predicate devices, SpiroPro® and QRS Diagnostic SpirOxCard, for Pulmonary Function and Pulse Oximetry respectively.

Pulmonary Function				
#	**Area**	**New Device: SpiroPro® SpO_2**	**Predicate Device: SpiroPro® (Pulmonary Function)**	**Same**
1	Indications for Use	Diagnostic Spirometry (Vcin, FVC, FEV1, MEF50 etc.)	Diagnostic Spirometry (Vcin, FVC, FEV1, MEF50 etc.)	X
2	Fundamental Scientific Technology	Pneumotachograph pressure to flow conversion technique	Pneumotachograph pressure to flow conversion technique	X
3	Disposable Accessories	Pneumotachograph set	Pneumotachograph set	X
4	Sterile / Non-Sterile	Non-Sterile	Non-Sterile	X
5	Patient Contact Materials	Plastic Mouthpiece	Plastic Mouthpiece	X
6	Off-the-Shelf Software required for use	Option	Option	X
7	Software Driven	Yes	Yes	X

Pulse Oximetry				
#	**Area**	**New Device: SpiroPro® SpO_2**	**Predicate Device: SpirOxCard® (Pulse Oximetry)**	**Same**
1	Indications for Use	Pulse Oximetry (Not for Continuous Use)	Pulse Oximetry (Not for Continuous Use)	X
2	Fundamental Scientific Technology	conventional dual wavelength pulse technique	conventional dual wavelength pulse technique	X
3	Accessories	Finger Clip Sensor	Finger Clip Sensor	X
4	Sterile / Non-Sterile	Non-Sterile	Non-Sterile	X
5	Patient Contact Materials	Plastic Finger Clip	Plastic Finger Clip	X
6	Software Driven	Yes	Yes	X

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Erich Jaeger GmbH
c/o Mr. Earl W. Draper
SensorMedics, Inc.
22705 Savi Ranch Parkway
Yorba Linda, CA 92887

Re: K031515
Trade/Device Name: SpiroPro SpO2
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, BTY
Dated: August 26, 2003
Received: August 28, 2003

Dear Mr. Draper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

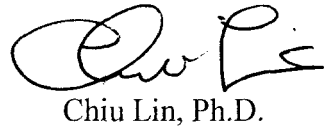
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K031515

Device Name: **SpiroPro SpO_2**

Indications For Use:

The SpiroPro SpO2 is a portable, battery operated device and can be used by physicians in the office or hospital, in occupational medicine or by patients in the home. The SpiroPro SpO2 measures inspiratory and expiratory lung function parameters in adults and children 4 years and older. In addition to the pulmonary function measurements, oxygen saturation and heart rate can be recorded.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K031515

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)